Urea Resins Group

SOCMA
Urea Resins Group

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December 3, 2001

RETURN RECEIPT REQUESTED VIA E-MAIL

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program; HPV Registration Number

Dear Administrator Whitman:

The Urea Resins Group is volunteering as an industry consortium to be a sponsor in the HPV Challenge. Several developments have occurred this year, which necessitates a change in our sponsorship. One of the original members, Sybron Chemicals, was acquired and is no longer part of our consortium. They were the only producer in the consortium of CAS# 3001-61-4. Since none of the remaining Group members produce or import this material, the SURG can no longer justify sponsorship of the chemical. The Group does, however, intend to fulfill its commitment to sponsor CAS# 68411-81-4.

Chemical	CAS#	Year
2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated	68411-81-4	2001

The Coalition members are Hickson DanChem Corporation, Noveon, Inc. and OMNOVA Solutions Inc. Although OMNOVA Solutions is not a producer or importer of CAS# 68411-81-4, the company feels strongly about working their counterparts in the general urea resins market to help provide valuable information to the public.

SURG is submitting its test plan for CAS# 68411-81-4 with this package. If there are any questions or comments, please feel free to contact me.

Sincerely,

James R. Cooper
Executive Director

cc: Urea Resins Group

AR201-13551A

TEST PLAN FOR METHYLATED 2-IMIDAZOLIDINONES

December 29, 2001

OVERVIEW

The Synthetic Urea Resins Group (SURG) of the Synthetic Organic Chemical Manufacturers Association. (SOCMA) hereby submits for review a test plan for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-61-4) under the Environmental Protection Agency's (EPA) High Production Volume (HPV) Chemical Challenge Program. It is the intent of the panel and its member companies to combine data on the methylated imidazolidinone with data on the well, studied non-methylated analog (2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-)(CAS No. 1854-26-8) to adequately fulfill the Screening Information Set (SIDS) endpoints. The non-methylated analog (CAS No. 1854-26-8) has already been reviewed as part of the OECD/SIDS program. Further comparison will be made between the methylated imidazolidinone and 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)-(CAS No. 3001-61-4), for which various physical/chemical and environmental fate properties can be estimated by modeling.

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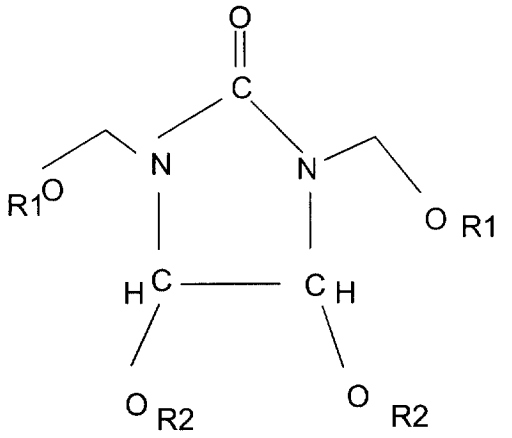
1. Information about the Panel

The Synthetic Urea Resins Group is formed under the sponsorship of the Synthetic Organic Chemical Manufacturers Association (SOCMA). The Panel consists of the following current or former manufacturers of methylated, substituted 2-imidazolidinone:

Hickson DanChem Corporation
Noveon, Inc.
OMNOVA Solutions Inc. (former manufacturer)

2. Identity of test substance and its analogs

The general molecular structure for the sponsored chemical and its analogs can be shown as follows"



Test Substance	Non-Methylated Analog	Dimethylated Analog
CAS # 68411-81-4	CAS # 1854-26-8	CAS #3001-61-4
R1, R2 = hydrogen and/or methyl	R1, R1 =hydrogen	R1 = methyl, R2 = hydrogen

The test substance, 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), is methylated to an undeternined extent. Methylation occurs primarily such that one or both R1 groups are methyl groups instead of hydrogen atoms. It is possible that some R2 groups are also methyl instead of hydrogen.

The primary (data rich) analog is 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). All R1s and R2s for this substance are hydrogen atoms. This substance has already been reviewed (SIAM 10) and been assigned a low priority for further work.

A second analog is 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-

61-4). For this substance, the R1s are methyl groups and the R2s are hydrogen atoms. Very limited data exist for this substance. However, this analog is useful because chemical/physical and environmental fate properties can be estimated for this substance by modeling. The data obtained by modeling help to predict the effect methylation has on these properties.
For simplicity in referring to the test substance and the two analogs, they will be designated,

"Methylated imidazolidinone" = CAS No. 68411-81-4 (the test substance)

"Non-methylated imidazolidinone" = CAS No. 1854-26-8 (the data-rich analog)

"Dimethylated imidazolidinone" = CAS No. 3001-61-4 (the analog useful for comparative modeling)

3. Background Information on the Test Substance and surrogate

The test substance is manufactured by the reaction of glyoxal, urea and formaldehyde followed by methylation using methanol.

Both the test substance and the surrogates are substituted 4,5-dihydroxy-1,3-hydroxymethyl-2-imidazolidinones that are used in textile manufacture as industrial intermediates to produce easy care fabrics. They are applied to textile cloth and cured to crosslink with the cellulose molecules in the cloth, so that the finished textile cloth will have "memory" to retain crease or other desired shape. The methylated test substance contains lower residual levels of formaldehyde compared to the non-methylated analog. Residual formaldehyde in these products is released during processing, therefore minimizing any potential consumer exposure.

4. Test Plan

It is the intention of the Synthetic Urea Resins Group of SOCMA, which includes the manufacturers of "methylated imidazolidinone" (CAS No. 68411-81-4) to use information on this substance, combined with available studies on the related "non-methylated imidazolidinone" (CAS No. 1854-26-8) to fulfill the screening information data needs. An IUCLID data set summarizing the available studies (with Klimisch codes) for CAS No. 1854-26-8 exists (IUCLID, 2000), as well as a SIAR. CAS No. 1854-26-8 was reviewed at SIAM 10, and assigned "low priority for further work." The following sections discuss individual endpoints and how they are to be addressed. Study details may be reviewed in the robust summary set for CAS No. 68411-81-4.

4.1 Chemical/Physical Properties

Chemical and physical property data for the related "non-methylated imidazolidinone" (CAS No. 1854-26-8) are also shown in Table 1. Values for the two materials are comparable, demonstrating close resemblance in chemical physical properties.

Chemical/Physical Property data for CAS No. 68411-81-4 are reported in Table 1. A melting point of -39° C has been determined using OECD Guide-line 102 "Melting Point/Melting Range"

under good laboratory practices (Tognucci, 2001a)(Table 1). A boiling point of 118.5° C at 980 hPa has been determined using OECD Guide-line 103 "Boiling Point/boiling Range" employing good laboratory practices (Tognucci, 2001b). A specific gravity of 1.30-1.31 @25°C is provided in the Material Safety Data Sheet from Noveon, Inc. (2001).

Table 1. Chemical/physical properties of substituted 2-imidazolidinones

Endpoint	Methylated imidazolidinone (CAS No. 68411-81-4)[1]	Dihydroxy imidazolidinone (CAS No. 1854-26-8)[2]
Melting point (° C)	-39	-35
Boiling point (° C)	118.5	106
Density	1.30- 1.31	1.36
Partition coefficient (log Kow)	-3.2	-2.2
Water solubility (g/l)	> 5000	Miscible
Vapor pressure	Similar to water	Similar to water

[1]The test substance had the following composition: ca. 84% CAS No. 68411-81-4; ca. 13% H_2O, and 0.18% formaldehyde (CAS No. 50-00-0)

[2] Data were obtained from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

A water solubility of > 5000 g/l at 20° C was determined using OECD Guide-line 105 "Water Solubility" (Tognucci, 2001d).

The vapor pressures of the neat test product or its analogs are not known. However, these materials are commercially available as aqueous concentrates, and therefore are likely to have vapor pressures similar to water (water vapor pressure = 23.79 mm Hg or 31.71 hPa @ 25 °C).

A Log Kow of -3.2 at 20° C has been calculated from the following equation (Tognucci, 2001c):

log Kow = log (n-octanol solubility/water solubility = (<3.25 g/l / >5000 g/l) = < -3.2

This equation used the value of >5000g/l water solubility previously determined, and the value of <3.25 g/l for the solubility in n-octanol. The n-octanol solubility of the test material was determined to be <3.25 g/l by adding 0.13-0.14 grams of test material to 40 ml n-octanol at room temperature and stirring. The result was incomplete dissolving and two phases.

The negative log Kow indicates a greater propensity for the methylated material to partition to water than organic solvents.

4.2 Environmental Fate Parameters

Modeling data discussed below suggest that the nonmethylated, methylated , and dimethylated 2-imidazolidinones will have similar environmental fate properties.

Environmental fate parameters for methylated 2-imidazolidinone (CAS No. 68411-81-4) were obtained using the EPIWIN Program. The test substance itself cannot be modeled, because it does not have a precise, defined molecular structure. Both nonmethylated 2-imidazolidinone

(CAS No.1854-26-8) and the dimethylated 2-imidazolidinone (CAS No. 3001-61-4), which have well defined molecular structures, can be modeled using EPIWIN. As discussed above, these surrogates have closely analogous molecular structures, which bracket the molecular structure of methylated 2-imidazolidinone. Therefore the modeled environmental fate parameters of the surrogates should correspond closely to estimated parameters for methylated 2-imidazolidinone.

The comparative modeled environmental fate parameters for nonmethylated 2-imidazolidinone and dimethylated 2-imidazolidinone are listed in Table 2. As can be seen from the table, the values for both nonmethylated and dimethylated materials in general have close similarity. It is reasonable to expect for methylated test substance that the hydroxyl rate constant will range from 73.2 to 94.5 E-12 cm^3/molecule-sec. Similarly, the photolysis half-life will be between 0.11-0.15 days. There is about a 10-fold difference in the two Henry's Law Constants, but assuming a value for methylated test material between the range of 1.09E-13 to 10.6E-12 would indicate that all three compounds would display a low tendency toward volatilization from water. Fugacity Level III modeling for both the nonmethylated and dimethylated materials shows close agreement for relative concentrations in air, water, soil and sediment compartments under equilibrium conditions. It is reasonable therefore to expect that the methylated substance will preferentially partition to water and soil. Although stability of the test substance in water has not been determined, the commercial form of the product is as an aqueous concentrate. From a practical standpoint, therefore, it is likely that the product does not hydrolyze readily at neutral pHs (at ambient temperatures).

Table 2. Environmental fate parameters for substituted 2-imidazolidinones*

Environmental Fate Parameter	Nonmethylated 2-imidazolidinone (CAS No. 1854-26-8)	Dimethylated 2-imidazolidinone (CAS No. 3001-61-4)
Photolysis Hydroxyl Rate Constant (cm3/molecule-sec)	73.195 E-12	94.5 E-12
Photolysis half-life (days)	0.146	0.113
Stability in Water	Qualitatively stable	Qualitatively stable
Henry's Law Constant (atm-m3/mole)	1.06E-12	1.09E-13
Level III Fugacity: Air	0.00133 %	5.66E-6 %
Water	42.8 %	45.3 %
Soil	57.1 %	54.6 %
Sediment	0.0638 %	0.0755 %

* The values in this table for the analogs are predictive of the methylated test material of interest (CAS No. 68411-81-4), which cannot be modeled because it does not possess a precisely defined molecular structure.

4.3 Biodegradation

No biodegradation studies have been found for methylated imidazolidinone. Four biodegradation studies have been identified for the non-methylated imidazolidinone. The results shown in Table 3 indicate inherent biodegradability for the non-methylated imidazolidinone.

The EPIWIN BIOWIN Program [Version (4.0)] conducted for the non-methylated substance qualitatively predicts that it biodegrades quickly. The same program conducted for the dimethylated analog predicts slow biodegradation. This comparison suggests that methylation may retard biodegradation to some extent, and that methylated imidazolidinone will biodegrade more slowly than the unmethylated surrogate. No further biodegradation testing is recommended for methylated imidazolidinone.

Table 3. Biodegradation for substituted 2-imidazolidinones*

Study	Nonmethylated 2-imidazolidinone (CAS No. 1854-26-8)	Dimethylated 2-imidazolidinone (CAS No. 3001-61-4)
Aerobic, activated sludge, non-adapted	60-70% after 28 day, "inherently biodegradable"[1]	-
Aerobic, activated sludge, non-adapted	27% after 8 days, 28% after 58 days[2]	-
Aerobic, activated sludge	38% after 28 days[3]	-
Activated sludge	70% after 2 months [4]	-
EPIWIN/BIOWIN (v4.00)	"biodegrades fast"	"Does not biodegrade fast"

* Data for the methylated test material of interest (CAS No. 68411-81-4) are not available

[1] BASF, 1996 .OECD Guideline 301. Test substance consisted of 73.9% active ingredient and 26.1% water.

[2] BASF, 1996 OECD Guideline 303. Test substance consisted of 73.9% active ingredient and 26.1% water.

[3] BASF, 1980b. Study remark: No oxygen consumption; elimination probably not due to biodegradation.

[4] BASF, 1974. Test substance consisted of 45 % active ingredient and 55 % water

4.4 Ecotoxicity

Results of ecotoxicity studies with the non-methylated imidazolidinone are summarized in Table 4. ECOSAR modeling predicts that both the non-methylated imidazolidinone and the dimethylated imidazolidinone exhibit low toxicity. Actual studies indicate low toxicity to fish, Daphnia and bacteria, and moderate to moderately high toxicity to algae. Although the ECOSAR predictions appear high in relation to the other studies, the modeling indicates that the presence or absence of methylation on the 1 and 3 hydroxymethyl positions does not have a significant bearing on aquatic toxicity. Therefore, it is reasonable to conclude that methylated imidazolidinone possesses a similar degree of toxicity as both non-methylated imidazolidinone and dimethylated imidazolidinone. Accordingly, no additional studies are recommended for the aquatic toxicity endpoints.

Table 4. Ecotoxicity Studies for substituted 2-imidazolidinones*

Endpoint	Non-methylated imidazolidinone (CAS No. 1854-26-8)	Dimethylated imidazolidinone (CAS No. 3001-61-4)
Acute toxicity to fish (96 hr LC_{50}, mg/l)	2200 [a] 3.6E+9 [b]	1.9E+7 [b]
Acute toxicity to Daphnia (48 hr LC_{50}, mg/l)	>500 [c,d] 2.23E+9 [b]	1.4E+9 [b]
Chronic toxicity to Daphnia (21 day NOEC, mg/l)	≥ 100 [c]	-
Toxicity to algae (EC_{50}, mg/l)	36.9 [c,f] 28.4[c,g] 8.85E+8 [b,g]	6.41E+6 [b,g]
Bacteria (mg/l)	2200 [c,h] > 1000[i] 1995[j]	-

* Data for the methylated test material of interest (CAS No. 68411-81-4) are not available. CAS No. 68411-81-4 cannot be modeled because it does not possess a precisely defined molecular structure.

[a] BASF, 1990. Active ingredient: 40%

[b] EPIWIN/ECOSAR Program (v0.99f).

[c] BASF, 1988. Active ingredient: 40%

[d] Directive 84/449/EEC, C.2 "Acute Toxicity for Daphnia"

[e] BASF, 1999; EEC Guideline XI/681/86. Active ingredient: 70%

[f] 72 hours; [g] 96 hours

[h] Growth Inhibition Test, DIN 38412/8. 17 hr EC50. Active ingredient: 40%

[i] BASF 1996c. OECD Guideline 209 "Activated Sludge, Respiration Inhibition Test". 30 min NOEC. Active ingredient: 74%

[j] BASF 1980a. Short term respiration test. Highest concentration of material tested with < 20 % inhibition in 30 min.

4.5 Human Health Data

Results of mammalian toxicity tests conducted on the non-methylated imidazolidinone are summarized in Table 5. These studies indicate that the material has a low potential for acute, repeated dose, reproductive or developmental toxicity. Based on the structural similarity of the methylated material with the non-methylated material, the methylated material is also expected to have a fairly low potential for acute, repeated dose, genetic, reproductive, or developmental toxicity.

Table 5. Mammalian Toxicity Data for substituted 2-imidazolidinones*

Endpoint	Non-methylated imidazolidinone (CAS No. 1854-26-8)	Reference
Acute oral (LD_{50}, mg/kg)[1]	≥ 2,880 (rat)[2] ≥ 10,000 (rat)[2] ≥ 10,000 (mouse)[2]	BASF, 1973 IRDC, 1983a IRDC, 1983b
Acute inhalation	No mortality after 8 or 1 hr exposure to saturated atmosphere @ 20 or 150 °C (respectively)	BASF, 1973
Repeated oral dose toxicity[3] (NOAEL, mg/kg/day)	4,000 (rat, 14 day) 1,000 (rat, 90 day) ≥ 11,680 (mouse, 14 day)[2] ≥ 6,000 (mouse, 90 day)[2]	IRDC, 1983a IRDC, 1983a IRDC, 1983b IRDC, 1983b
In vitro genetic toxicity (Ames)	TA97, TA98, TA 1535, TA1537, and TA102 -negative TA100 - equivocal	Zeiger et al., 1987 CCR, 1992; NTP, 1984 NTP, 1984; Zeiger et al., 1987
In vivo genetic toxicity	Mouse micronucleus at 2000 mg/kg - negative Sex linked recessive lethal at 60000 ppm in Drosophila - positive Reciprocal translocation at 50000 ppm in Drosophila - negative	Biopharm, 1995 Foureman et al., 1994 Foureman et al., 1994
Reproductive toxicity[3,4] (NOAEL, mg/kg)	3,000 (rat) ≥ 6,000 (mouse)[2]	IRDC, 1983a IRDC, 1983b
Developmental toxicity[1] (NOAEL, mg/kg)	≥ 640 (rat)[2]	HMR, 1998

* Data for the methylated test material of interest (CAS No. 68411-81-4) and dimethylated imidazolidinone (CAS No. 3001-61-4) are not available

[1] Values refer to 100% test material

[2] Highest dose used

[3] Test material contained 41.4% CAS No. 1854-26-8

[4] Examination of reproductive organs from 90-day study

4.5.1 Acute Toxicity

Acute toxicity testing has not been conducted for the methylated imidazolidinone. Two acute oral studies for the rat and one for the mouse have been performed and summarized for the nonmethylated imidazolidinone. LD_{50} values ranged from >2,880 to >10,000 mg/kg. In mice receiving 2880 mg/kg by i.p. injection, the only symptoms observed were dyspnea and atony. Macroscopic inspection showed no pathological findings (BASF, 1973).

At ambient temperature, inhalation exposure for 8 hr to an atmosphere highly enriched in vapors from a 45 % aqueous solution (Fixapret CPN) caused no lethality, but caused dyspnea and irritation of mucous membranes (BASF, 1973). Vapors generated at 150° C produced severe irritation and dyspnea and were lethal to rats within a few hours (BASF, 1973). Spot-like hyperemia and edema of the lung were prominent, while hydrothorax was seen in isolated cases. It is assumed that decomposition products arising at temperatures greater than 40° C induced these serious effects (SIAR for CAS No. 1854-26-8; reviewed at SIAM 10).

Based on the structural similarity of the methylated material (CAS No. 68411-81-4) with the non-methylated material (CAS No. 1854-26-8), it is likely that the methylated material would also have fairly low acute oral and inhalation toxicity.

4.5.2 Repeated Dose Toxicity

No repeated dose studies have been identified for the methylated imidazolidinone (CAS No. 68411-81-4). Repeated dose studies are available in the rat and mouse for the related non-methylated imidazolidinone (CAS No. 1854-26-8)(Table 5). Fourteen-day oral (gavage) studies in rats and mice were conducted at doses ranging from 256 to 11,600 mg/kg/day (IRDC, 1983a,b). No test-related toxicologically significant macroscopic lesions or abnormalities were observed in rats or mice treated with any dose (with the exception of a moderately inflammatory bilateral reaction in the nasal passages of rats treated with 11,600 mg/kg).

Ninety-day oral (gavage) studies have been run in both the rat and the mouse for the non-methylated analog (CAS No. 1854-26-8)(Table 5) (IRDC, 1983a,b). Dose levels were 1000, 3000 and 6000 mg/kg/day of a material containing 41.4% CAS No. 1854-26-8. Pharmacotoxic signs noted for male and female rats in the 3000 and 6000 mg/kg/day dosage level groups including discoloration of the fur, soft stool, hypoactivity, decreased grasping reflex, ataxia, and decreased temperature of extremities. No deaths were reported and no toxicologically significant organ weight changes were observed. On postmortum examination, mild to moderate mineralization was observed in the heart and testes of two male rats, and multiple yellowish linear macroscopic lesions were observed in the right testis of one male rat treated with 6000 mg/kg/day.

In the 90-day mouse study, females of all dose groups and males at 1000 and 6000 mg/kg/day dose groups showed increased weight gains compared to controls (not toxicologically significant). The 6000 mg/kg/day group and controls showed no microscopically visible changes (the animals of the

1000 and 3000 mg/kg/day doses were not examined). One death occurred in the 3000 mg/kg male dose group at week three that was not considered treatment related.

The above studies are indicative of generally low repeated dose toxicity of non-methylated imidazolidinone (CAS No. 1854-26-8), even when adjusting the effective dose downward in the 90-day studies to reflect the 41.4% concentration of active ingredient. Based on the close structural similarity of non-methylated and methylated imidazolidinones, it is reasonable to conclude that the repeated dose toxicity of the methylated material (CAS No. 68411-81-4) would not differ significantly from that of the non-methylated material.

4.5.3 Genetic Toxicity

No genotoxicity studies have been identified for methylated imidazolidinone (CAS No. 68411-81-4). Three Ames tests are reported and summarized for non-methylated imidazolidinone (CAS No. 1854-26-8) (Zeiger et al., 1987; CCR, 1992; NTP, 1984). The tests show that non-methylated analog was negative in Salmonella strains TA1535, TA1537, and TA102 in the presence and absence of metabolic activation. However, results of the study by Zeiger et al., 1984 (which was conducted in two different laboratories) are equivocal for strains TA98 and TA100. In the presence of S-9, approximately 50% of tests in strain TA100 were questionable in one laboratory (with test material in DMSO) and all tests were positive in the other laboratory (with test material in water). Weakly positive or questionable results were found in strain TA98 in the presence or absence of S-9 in the same laboratory that found positive results in strain TA100 (material was in water). One out of five tests in the other laboratory with strain TA98 in the presence of S-9 (and test material in DMSO) showed a weak response. Because the tests with the two solvents were performed in different laboratories, it is difficult to discern whether the variable results were due to the tests being conducted in different laboratories or the use of different solvents.

Three *in vivo* genetic toxicity studies have been conducted in Drosophila melanogaster [two sex linked recessive lethal (SLR) and one reciprocal translocation)] with non-methylated imidazolidinone (Foureman et al., 1994). At a very high concentration of 60000 ppm (either orally or by i.p. injection), the test material induced a four-fold increase in sex-linked recessive lethal events. However, oral administration of a similar concentration (50000 ppm) did not lead to an increase in reciprocal translocations. Because the only concentration used in the sex-linked Drosophila study was very high, it is not known whether these effects occur at lower, more realistic exposure concentrations. Furthermore, due to study deficiencies, the sex-linked Drosophila study was assigned a reliability rating of 4. The Ames study is considered to be a more reliable test for assessing genotoxic potential of CAS No. 1854-26-8.

A mouse micronucleus study conducted on CAS No. 1854-26-8 under OECD Guideline 474, (using good laboratory practices) indicated that the test material did not increase the frequency of micronuclei at 2000 mg/kg (Biopharm, 1995).

The above studies are indicative of low potential for non-methylated imidazolidinone (CAS No. 1854-26-8) to produce genotoxicity. Only high doses of the material (generally 3333 mg/plate or higher) were shown to be mutagenic in some strains in the presence of S-9. Based on the close structural similarity of non-methylated and methylated imidazolidinones, the in vitro genetic

toxicity profile of the methylated material (CAS No. 68411-81-4) is not expected to differ significantly from that of the non-methylated material. Also, because the material is largely excreted unchanged in the urine upon oral administration and is not absorbed well from the skin (see Toxicokinetics below), the potential for DNA-reactive metabolites to be formed after in vivo exposure is low. Therefore, no additional in vitro testing is planned.

4.5.4 Reproductive Toxicity

No reproductive toxicity study has been identified for methylated imidazolidinone (CAS No. 68411-81-4). However, ninety-day oral (gavage) toxicity studies (that included examination of the reproductive organs of both sexes) on a material containing 41.4% of the non-methylated analog (CAS No. 1854-26-8) have been conducted in rats and mice (IRDC, 1983a,b). Microscopic inspection of these organs (including testes, epididymis, prostate, preputial gland/uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities. No histopathological changes were observed up to 3000 mg/kg/day in male rats and up to 6000 mg/kg/day in female rats. No changes were seen up to 6000 mg/kg/day in both genders of mice. These studies are predictive of low reproductive toxicity for the methylated imidazolidinone. No additional studies are planned for this endpoint.

4.5.5 Developmental Toxicity

No developmental toxicity study has been identified for methylated imidazolidinone (CAS No. 68411-81-4). Teratogenicity testing has been conducted for non-methylated imidazolidinone (CAS No. 1854-26-8) in pregnant Wistar rats, following OECD Guideline 414 (HMR, 1998)(Table 5). No compound- related effects were observed at doses up to 1000 mg/kg. Since the test substance was 61.4% CAS No. 1854-26-8 in water, a NOAEL of 640 mg/kg was determined for both maternal toxicity and teratogenicity. Based on the structural similarity of the methylated imidazolidinone to the non-methylated material, this study should be predictive of developmental toxicity for methylated imidazolidinone. Therefore, no further testing is planned.

4.5.6 Other

4.5.6.1 Skin and eye irritation

No skin and eye irritation studies have been identified for methylated imidazolidinone (CAS No. 68411-81-4). Irritation studies are available for non-methylated imidazolidinone (CAS No. 1854-26-8). One skin irritation study (BASF, 1973) using the rabbit showed no irritation, and a secondary reference (Marhold [1972] in Czech) cited in RTECs indicated severe irritation. One eye irritation study, using the rabbit, showed no irritation (BASF, 1973), whereas the same secondary RTECs Czech reference noted above indicated mild irritation. The BASF study is identified as the critical, valid study for this endpoint. Therefore, it is concluded that CAS No. 1854-26-8 is not highly irritating to the skin and eye. Based on the structural similarities between the methylated and nonmethylated material, strong skin and eye irritation is not likely to be associated with the methylated imidazolidinone (CAS No. 68411-81-4).

4.5.6.2 Sensitization

Human experience data with methylated imidazolidinone (CAS No. 68411-81-4) is limited. However, none of the sponsors identified any reports of skin sensitization in people who work with this material. Several cases of skin sensitization, dermatitis or eczema have been reported in humans who have contacted resin-treated textiles (Malten, 1964; Andersen and Harman, 1982; Tegner, 1985; Fregert and Tegner, 1971; Hatch and Maibach, 1986, Scheman et al., 1998; Sommer et al., 1999; BG Chemie, 1995;). Many of the examined cases showed patch test results to both CAS No. 1854-26-8 and formaldehyde (a probable contaminant). Because the methylated imidazolidinone used for patch testing was not analyzed in any of the studies, one cannot conclude that the methylated imidazolidinone (and not contaminating formaldehyde) was the sensitizer. Because the methylated material is less likely to release formaldehyde than the nonmethylated material, the potential for sensitization to occur due to formaldehyde exposure is expected to be low.

4.5.6.3 Toxicokinetics

Results of studies in rats and monkeys indicate that non-methylated imidazolidinone (CAS No. 1854-26-8) is poorly absorbed from the skin (Jeffcoat, 1984; 1985). Hydration of the skin increases absorption. After oral or intravenous administration, the material is quickly distributed to the skin, muscle, blood, liver and kidney (Robbins et al., 1984, Robbins and Norred, 1984; Jeffcoat, 1985). Within 24-hours of oral or intravenous administration, the vast majority of the material is excreted unchanged in the urine (Jeffcoat, 1985). Based on the structural similarities between the methylated and nonmethylated material, the methylated imidazolidinone (CAS No. 68411-81-4) is likely to have a similar pharmacokinetic profile as the nonmethylated material.

5. Summary

In summary, based on the structural/physical similarities and chemical physical between methylated imidazolidinone (CAS No. 68411-81-4), dimethylated material (CAS No. 3001-61-4), and non-methylated imidazolidinone (CAS No. 1854-26-8), the data for the non-methylated and dimethylated materials will be predictive of toxicity for the methylated material. Physical/chemistry data for the actual test material, modeled environmental fate data for the dimethylated material (CAS No. 3001-61-4) and experimental ecotoxicity and mammalian toxicity data for the nonmethylated material are present to satisfy all endpoints (Tables 6 and 7). No further testing is planned.

Table 6. Test Plan

CAS **No. 68411-81-4**	Information	OECD Study	Other	Estimation	GLP	Acceptable	New Testing Required
ENDPOINT	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYS/CHEM PROPERTIES							
Melting Point	Y	Y	N	N	Y	Y	N
Boiling Point	Y	Y	N	Y	Y	Y	N
Vapor Pressure	Y[1]	N	N	N	N	N	N
Partition Coefficient	Y	N	Y	N	Y	Y	N
Water Solubility	Y	Y	N	N	Y	Y	N
ENVIRONMENTAL FATE							
Photodegradation	Y*	N	Y	Y	N	Y	N
Stability in Water	Y[2]	N	N	N	N	N	N
Biodegradation	Y*	Y	N	N	Y	Y	N
Transport between Environmental Compartments (Fugacity)	Y*	N	Y	Y	N	Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y*	N	Y	N	N	Y	N
Acute Toxicity to Aquatic Invertebrates	Y*	N	Y	N	N	Y	N
Toxicity to Aquatic Plants	Y*	N	Y	N	N	Y	N
TOXICOLOGICAL DATA							
Acute Toxicity	Y*	N	Y	N	N	N	N
Repeated Dose Toxicity	Y*	Y	N	N	N	Y	N
Genetic Toxicity-Mutation	Y*	N	Y	N	N	N	N
Genetic Toxicity-Chromosomal Aberrations (mouse micronucleus)	Y*	Y	N	N	Y	Y	N
Toxicity to Reproduction	Y*	N	Y	N	N	Y	N
Developmental Toxicity	Y*	Y	N	N	Y	Y	N
OTHER TOXICITY DATA							
Skin Irritation	Y*	N	Y	N	N	Y	N
Eye Irritation	Y*	N	Y	N	N	Y	N
Skin Sensitization	Y*	N	Y	N	N	Y	N
Absorption	Y*	N	Y	N	N	Y	N

*Data on surrogate chemical (CAS No. 1854-26-8) are used

[1] Actual value is not known; however is likely to be close to that of water, since the product is commercially available as an aqueous concentrate.

[2] Actual value is not known; however material is likely to be stable in water because it is sold in the form of an aqueous concentrate.

Table 7. Analog Matrix for 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated*

ENDPOINT	68411-81-4 (Methylated) (Test substance)	1854-26-8 (Non-methylated) (Analog)	3001-61-4 (Dimethylated) (Analog)
PHYSICAL CHEMISTRY			
Melting point	A	A	NR
Boiling point	A	A	NR
Density	A	A	NR
Vapor Pressure	E	E	NR
Water Solubility	A	A	NR
Kow	A	A	NR
ENVIRONMENTAL FATE			
Photodegradation	R	Calc.	Calc.
Stability in Water	E	E	NR
Biodegradation	R	A & Calc.	Calc.
Transport between Environmental Compartments (Fugacity)	R	Calc.	Calc.
ECOTOXICITY			
Acute Toxicity to Fish	R	A & Calc.	Calc.
Acute Toxicity to Aquatic Invertebrates	R	A & Calc.	Calc.
Toxicity to Aquatic Plants	R	A & Calc.	Calc.
TOXICOLOGICAL DATA			
Acute Toxicity	R	A	NR
Repeated Dose Toxicity	R	A	NR
Genetic Toxicity-Mutation	R	A	NR
Genetic Toxicity-Chromosomal Aberrations	R	A	NR
Carcinogenicity (NR)	NR	NR	NR
Toxicity to Reproduction	R	A	NR
Developmental Toxicity	R	A	NR
OTHER TOXICITY DATA			
Skin Irritation (NR)	R	A	NR
Eye Irritation (NR)	R	A	NR
Skin Sensitization (NR)	R	A	NR
Toxicokinetics (NR)	R	A	NR

* Data on analogs CAS No. 1854-26-8 and 3001-61-4 are shown for comparison.
R = Required endpoint fulfilled by surrogate, SAR; Test = Testing planned to fulfill requirement; Calc. = Calculated value; E = estimated qualitatively; A = Adequate existing data; NR = Not required

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7. Appendix 1- Robust Summaries

AR201-13551B

IUCLID

Data Set

Existing Chemical	:	ID: 68411-81-4
CAS No.	:	68411-81-4
Producer Related Part		
Company	:	PCA Services, Inc.
Creation date	:	28.10.2001
Substance Related Part		
Company	:	PCA Services, Inc.
Creation date	:	28.10.2001
Memo	:	
Printing date	:	21.12.2001
Revision date	:	
Date of last Update	:	21.12.2001
Number of Pages	:	37
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5,

1.0.1 OECD AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

2-Imidazolidinon, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methyliert
28.10.2001

2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidinone, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidone, methylee
28.10.2001

Dihydroxydimethylolethyleneurea, methylated
28.10.2001

Dimethylolglyoxalmonoureine, methylated
28.10.2001

Dimethylolglyoxalurea, methylated
28.10.2001

Imidazolidinone-2, dihydroxy-4,5-bis(hydroxymethyl)-1,3, methylee
28.10.2001

1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

Type	:	industrial
Category	:	Textile processing industry
Reliability	:	(1) valid without restriction

28.10.2001

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

Value	:	= -39 ° C
Decomposition	:	no at ° C
Sublimation	:	no
Method	:	OECD Guide-line 102 "Melting Point/Melting Range"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	At room temperature the test material was clear, colored yellow, viscous and the magnetic agitator was stirring. The test material was cooled down and at about -14 degrees C the agitator stopped stirring. The cooling was continued and at about -25 degrees C the viscosity increased. The freezing point was observed between -18.5 and -19.5 degrees C. A determination of the freezing temperature with a thermocouple showed no relevant heat effect.
Test substance	:	The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (present at about 84% concentration). The purity of test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) of formaldehyde may have been present.
Reliability	:	(1) valid without restriction.

28.10.2001 (32)

2.2 BOILING POINT

Value	:	= 118.5 ° C at 980 hPa
Decomposition	:	no
Method	:	OECD Guide-line 103 "Boiling Point/Boiling Range"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Both a thermal analysis (using a differential scanning calorimeter) and visual tests (using a capillary tester) were employed for this determination.
Test condition	:	A phase transformation, e.g., evaporation, is usually associated with a heat effect. In a preliminary study, two identical aluminum sample containers, one filled with the test material and the other empty (used as a reference),were heated in the calorimeter at a constant rate. During a preliminary experiment, the heat effect (i.e., the difference in the heat flow between the sample container and the reference container) was registered. In the main study, a small amount of the test item was filled into two small glass tubes and boiling capillaries were inserted. The samples were heated simultaneously from 25 degrees C to about 190 degrees C. The heating rate was reduced to 10 degrees Kelvin/min. The samples were observed visually through a lens. A current stream of bubbles from the capillary indicated the boiling point. The study was performed at local atmospheric pressure (980 hPa).
Result	:	The Differential Scanning Calorimeter (DSC) curve of the preliminary test (heating rate of 20 degrees Kelvin/min from 25-400 degrees C) was recorded. An endothermic heat effect was observed starting at about 70 degrees C. As the endothermic peak was not well defined, the main study

was performed using the capillary tester. After the preliminary test, the sample had lost about 70% of its mass and the residue sample was foamed and black in color. The temperature range of the endotherm was about 70-220 degrees C.

In the main test (using the capillaries and visual examination) the primary boiling range was determined to be 118.5 +-0.2 degrees C. The sample became darker while boiling but remained clear, indicating only minor decomposition.

Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Reliability : (1) valid without restriction .
28.10.2001 (33)

2.3 DENSITY

Value : 1.30-1.31g/ml
Method : unknown
Year :
GLP : no data
Test substance : Freerez® MTH Conc.
Reliability : (2) valid with restrictions. Manufacturer's MSDS. Method not given.
28.10.2001 (25)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

Log Pow : = -3.2 at 20° C
Method other (calculated)
Year : 2001
GLP : yes
Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Remark : Neither the HPLC-method according to OECD Guideline No. 117 nor the flask-shaking method according to OECD Guideline No. 107 were applicable for the determination of the partition coefficient of Freerez® MTH Conc. Thus the log Pow-value for the test item was estimated from its solubility in n-octanol and water, respectively.

Test condition : The n-octanol solubility of the test material was determined to be < 3.25 g/l by adding 0.13-0.14 grams of test material to 40 ml n-octanol at room temperature and stirring. The result was incomplete dissolving and two phases. The water solubility of the test item was estimated to be > 5000 g/l

in another study (see Section 2.6.1 below). The Log Pow was then calculated using the following equation:

log Pow = log (<3.25 g/l / >5000 g/l) = < -3.2

Reliability : (1) valid without restriction.
28.10.2001

(34)

2.6.1 WATER SOLUBILITY

Value	:	> 5000 g/l at 20 ° C
Qualitative	:	
Pka	:	at 25 ° C
PH	:	at and ° C
Method	:	OECD Guide-line 105 "Water Solubility"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	The water solubility of test material at room temperature was estimated by a simplified flask method.
Result	:	The saturated concentration was not reached, but this test indicates that the test substance is miscible in any ratio with water.
Test condition	:	1 ml of water was stepwise mixed with a total amount of 5 g of Freerez® MTH Conc. This mixture was stirred at room temperature for about 24 hours. The visual observation indicated one clear, light yellow phase. The test was performed in duplicate.
Test substance	:	The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.
Reliability	:	(1) valid without restriction

28.10.2001

(35)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	Sun light
Light spect.	:	nm
Rel. intensity	:	based on Intensity of Sunlight
Direct photolysis		
Halflife t1/2	:	ca. 1.8 - 1.4 hour(s)
Degradation	:	% after
Quantum yield	:	
Indirect photolysis		
Sensitizer	:	OH
Conc. of sens.	:	
Rate constant	:	cm^3/(molecule*sec)
Degradation	:	% after
Deg. Product	:	
Method	:	other (calculated)
Year	:	2001
GLP	:	not applicable
Test substance	:	other TS
Result	:	The hydroxyl rate constant was estimated to be from 73.2 - 94.5 E-12 cm^3/molecule-sec. The first value is the rate constant calculated by EPIWIN for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), and the second value is the rate constant calculated for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Test condition	:	Photodegradation parameters were estimated using the EPIWIN/AOP Program (v1.90). This program uses an algorithm to sum up individual photodegradation rate constants for the different chemical bonds within the test substance molecule and the molecular weight. The photodegradation half-life was calculated assuming that the hydroxyl radical concentration is constant and using pseudo first order kinetics. The test substance itself could be modeled, because it is does not have a precisely defined molecular structure. It is denoted to be "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-. Therefore, the following analogous substances were modeled: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). These two analogs bound the test material, because it is partially to completely methylated in the 1,3 positions. Thus, the hydrolysis rate constant and the atmospheric half-life of the test material lies somewhere in between values for these parameters possessed by the non-methylated and bis methylated analogs. The values assigned to the test between the values calculated for the analogs.
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Reliability	:	(2) valid with restrictions. Data were obtained by modeling with related chemicals

28.10.2001

3.1.2 STABILITY IN WATER

Remark	:	Water stability for the test material cannot be calculated with EPIWIN. EPIWIN states merely that hydrolysis will occur slowly for the urea function in the molecule, but does not comment on the other functions in the molecule. The test material is present in a proprietary mixture (Freerez® MTH Conc.) as an aqueous concentrate. Therefore it must be reasonably stable in water. There are no functional groups present in the molecule that would be expected to hydrolyze easily.
Reliability	:	(4) not assignable

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	water - air
Air (level I)	:	0
Water (level I)	:	45.3
Soil (level I)	:	54.6
Biota (level II / III)	:	.0755
Soil (level II / III)	:	
Method	:	other
Year	:	2001
GLP	:	not applicable
Test substance	:	other TS
Remark	:	Mackay Level III Fugacity modeling was also conducted on the unmethylated CAS No.1854-26-8, with the following equilibrium concentrations in the environmental compartments: Air: 0.00133% Water: 42.8% Soil: 57.1% Sediment: 0.0638 These values are very close to those of the dimethylated material.
Result	:	The Henry's Law Constants calculated by EPIWIN Henry (v3.10) for the dimethylated and non-methylated analogs of the test substance are as follows: 2-imidazolidinone, 4,5-dihydroxy-1.3-bis(hydroxymethyl)- (CAS No. 1854-26-8) = 1.06E-12. 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4) = 1.09E-13. Based on the test substance's partial to complete methylation on the 1 and

3 positions, its Henry's Law Constant is likely to lie between the above two values.

Test condition : The EPIWIN Program was used to conduct MacKay Level III Fugacity modeling for the test substance. The test substance itself was not modeled, because it does not possess a precise molecular structure. The test substance is "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- CAS No. 68411-81-4, which indicates that it is partially to completely methylated in the 1 and 3 positions. The extent of methylation is undefined for the test substance. For this reason Level III fugacity modeling was conducted for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). This material is completely methylated on both the 1 and 3 positions.

Conclusion : Given the values obtained by modeling both the unmethylated and completely methylated materials, one might conclude with reasonable confidence that the test substance partitions preferentially to water and soil. That conclusion is further supported by the test substances miscibility with water and its moderate volatility.

Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Reliability : (2) valid with restrictions. Data were obtained by modeling with a related chemical.

28.10.2001

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge, industrial
Concentration	:	400 mg/l related to DOC (Dissolved Organic Carbon) related to
Contact time	:	
Degradation	:	= 38% after 28 day
Result	:	
Kinetic of test substance	:	3 hour(s) = 5 % 1 day = 11 % 6 day = 31 % 13 day = 38 % %
Deg. Product	:	
Method	:	Other: Standversuch
Year	:	1980
GLP	:	no

Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	No oxygen consumption; elimination probably not due to biodegradation.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(7)

Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	50 mg/l related to Test substance
Contact time	:	
Degradation	:	> 70% after 2 month
Result	:	other: biodegradable
Deg. Product	:	
Method	:	other: OECD-Confirmatory-Test
Year	:	1974
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), about 45 per cent solution in water.
Remark	:	Remark in IUCLID file states that the test report contained very few data
Reliability	:	(4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(2)

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Concentration	:	10 mg/l related to DOC (Dissolved Organic Carbon)
Degradation	:	= 60-70% after 28 days
Result	:	inherently biodegradable
Kinetic	:	28 day = 60-70 % 49 day = 70-80 %
Method	:	OECD Guide-line 301A (new version) "Ready Biodegradability: DOC Die Away Test"
Year	:	1993
GLP	:	yes
Test substance	:	Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3 bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition	:	Medium: water
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(10)

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Concentration	:	20 mg/l related to DOC (Dissolved Organic Carbon)
Degradation	:	Ca. 27% after 8 day
Result	:	inherently biodegradable
Kinetic	:	5 day = 14% 8 day = 20% 58 day = 28%

Method	:	OECD Guide-line 303A "Simulation Test- Aerobic Sewage Treatment: Coupled Unit Test"
Year	:	1993
GLP	:	yes
Test substance	:	Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3 bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition	:	Medium: water
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(11)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Elimination	:	
Method	:	other
Year	:	
GLP	:	
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Due to the water solubility and the measured log Pow of the compound the potential for bioaccumulation is low.
Reliability	:	(4) not assignable. No experimental data is available. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Leuciscus idus (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
NOEC	:	1000
LC50	:	ca. 2200
LC100	:	4640
Method	:	other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN 38 412 Teil 15
Year	:	1982
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark	:	Symptoms: Apathy, tumbling
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(3)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	
EC0	:	= 500
EC50	:	> 500
EC100	:	> 500
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark	:	Same results when exposure period = 24 h.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	other: comparison of cell density at the end of test
Exposure period	:	72 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC50	:	= 36.9
EC20	:	= 22.9

Method	:	other: "Algentest in Anlehnung UBA"
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.
Remark	:	EC90(72h)=158.7 mg/l.
Test condition	:	illumination: intensity =120 Mikroeinstein/mxmxs; permanent
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	other: comparison of cell density at the end of test
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC50	:	= 28.4
EC20	:	= 19.2
Method	:	other: "Algentest in Anlehnung UBA"
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.
Remark	:	EC90(96h)=68.9 mg/l.
Test condition	:	illumination: intensity =120 Mikroeinstein/mxmxs; permanent
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type	:	aquatic
Species	:	activated sludge, industrial
Exposure period	:	30 minute(s)
Unit	:	mg/l
Analytical monitoring	:	no data
EC50	:	= 280
EC20	:	= 180
EC80	:	= 450
Method	:	other: Short term respiration test
Year	:	1980
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Effect: stimulation of respiration; highest tested concentration with <20% respiration inhibition =1995 mg/l.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(5)

Type	:	aquatic
Species	:	Pseudomonas putida (Bacteria)
Exposure period	:	17 hour(s)

Unit	:	mg/l
Analytical monitoring	:	
EC10	:	= 1260
EC50	:	= 2200
EC90	:	= 4490
Method	:	other: growth inhibition test according to Bringmann-Kuehn, DIN 38412/8 (draft)
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

Type	:	aquatic
Species	:	other bacteria: activated sludge, municipal
Exposure period	:	30 minute(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC10	:	> = 1000
EC50	:	> = 1000
EC90	:	> = 1000
Method	:	OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year	:	1993
GLP	:	yes
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 74%.
Remark	:	No toxic effects were observed for highest concentration tested (1000 mg/l substance)
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(8)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species	:	Daphnia magna (Crustacea)
Endpoint	:	reproduction rate
Exposure period	:	21 day
Unit	:	mg/l
Analytical monitoring	:	no data
NOEC	:	>= 100
LOEC	:	>= 100
Method	:	other: EG- Richtlinie XI/681/86
Year	:	1986
GLP	:	yes
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 70%.

Remark	:	21 day semistatic test according to EEC guideline XI/681/86, Draft 4; test substance was tested in the range 0.2 to 100 mg/l, the dilution factor was 2. As test criteria, the reproduction and mortality of the test animals are given.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(9)

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Species	:	rat
Strain	:	unknown
Sex	:	unknown
Number of animals	:	unknown
Vehicle	:	water
Value	:	> 2880 mg/kg bw
Method	:	other: BASF test
Year	:	1973
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Remark	:	LD50 value refers to 100% substance. No toxic symptoms.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Type	:	LD50
Species	:	rat
Strain	:	unknown
Sex	:	unknown
Number of animals	:	unknown
Vehicle	:	water
Value	:	> 10000 mg/kg bw
Method	:	other: no further details given
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.5% in water, with 0.3% formaldehyde present
Remark	:	Pre-test for subchronic study. LD50 value refers to 100% substance
Result	:	Post-mortem examination revealed no macroscopic changes
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(20)

Type	:	LD50
Species	:	mouse
Strain	:	unknown
Sex	:	unknown
Number of animals	:	unknown
Vehicle	:	water
Value	:	> 10000 mg/kg bw
Method	:	other: no further details given
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.5% in water, with 0.3% formaldehyde present
Remark	:	Pre-test for subchronic study. LD50 value refers to 100% substance
Result	:	Post-mortem examination revealed no macroscopic changes

Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(19)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	other: IRT
Species	:	rat
Strain	:	unknown
Sex	:	unknown
Number of animals	:	unknown
Vehicle	:	unknown
Exposure time	:	8 hour(s)
Method	:	other: BASF test
Year	:	1973
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water (Fixapret CPN)
Result	:	No mortality after 8 hours of exposure to an atmosphere enriched or saturated at 20 degrees C. Mild signs of irritation of mucous membranes and dyspnea were observed.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type	:	LD50
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Route of admin.	:	i.p.
Exposure time	:	
Value	:	> 2880 mg/kg bw
Method	:	other: BASF test
Year	:	1974
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), probably 45% solution in water (Fixapret CPN)
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	not irritating
Method	:	other: BASF-Test
Year	:	1974
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	
EC classification	:	
Method	:	other: according to "Marhold"
Year	:	
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Effect: "severe"
Reliability	:	(4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(24)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	not irritating
EC classification	:	not irritating
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water

Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	
EC classification	:	
Method	:	other: according to "Marhold"
Year	:	
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Effect: "mild"
Reliability	:	(4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(24)

5.3 SENSITIZATION

Type	:	Patch-Test
Species	:	human
Concentration	:	Challenge 50%
Number of animals	:	
Vehicle	:	water
Result	:	
Classification	:	
Method	:	other: clinical test series
Year	:	1958
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (50% in aqueous solution)
Remark	:	Study is also described in Section 5.11
Result	:	Twenty seven out of 66 responded positively to various textile finishes and additives within 48 hr. Eight out of 24 tested with test substance gave a positive response. Six out of 8 also showed a positive reaction to formaldehyde (5% in aqueous solution).
Test condition	:	Thirty seven substances used in textile finishes (including the test substance) were patch-tested in 66 subjects who anamnestically and/or clinically were suspected of suffering from textile finish contact eczema.
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

25.10.2001

(23)

Type	:	Patch-Test
Species	:	human
Concentration	:	Challenge 10 %
Vehicle	:	Petrolatum
Method	:	other: clinical test series
Year	:	1980

GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (10 % in petrolatum) . The test materials contained some free formaldehyde (amount not specified).
Remark	:	The test material was not checked for autopolymerization or content of allergenic substances. The Calaroc resins are no longer available. Study is also described in Section 5.11
Result	:	The Calaroc PG and PK induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde.
Test condition	:	Four hundred twenty eight eczema patients were patch tested with textile finish resins from 1970 to 1980 (including test material). Fifteen out of the 428 had allergic textile dermatitis based on history, clinical features and patch test results. Three different resins containing test material in 10% petrolatum were patch tested [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] on ten of these subjects. Formaldehyde (2% in aqueous solution) was tested on all 15.
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

25.10.2001 (1)(12)(17)

Type	:	Patch-Test
Species	:	human
Concentration	:	Challenge
Number of animals	:	
Vehicle	:	no data
Result	:	
Classification	:	
Method	:	other: clinical test series
Year	:	1985
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark	:	Study is also described in Section 5.11
Result	:	One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Percent test material used is unknown. Original reference (16) was not consulted.

25.10.2001 (17)(16)

Type	:	Patch-Test
Species	:	human
Concentration	:	Challenge
Number of animals	:	
Vehicle	:	no data
Result	:	
Classification	:	
Method	:	other: clinical test series
Year	:	
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Study is also described in Section 5.11
Result	:	One out of 6 subjects reacted to the test substance; none responded to

formaldehyde.

Test condition	:	Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

25.10.2001 (31)

Type	:	Patch-Test
Species	:	human
Concentration	:	Challenge 4.5%
Number of animals	:	
Vehicle	:	water
Result	:	
Classification	:	
Method	:	other: clinical test series
Year	:	
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (4.5% in aqueous solution); Fixapret CPN
Remark	:	In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals. Study is also described in Section 5.11
Result	:	All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.
Test condition	:	Ten out of 12 subjects with known positive patch test reactions to older formaldehyde resins were patch-tested with commercial allergens, formaldehyde (1% in aqueous solution), older formaldehyde resins (including Fixapret CPN) and 6 newer, low-formaldehyde (< 200 ppm) resins (Fixapret ECO and NF (no formaldehyde), Freerez PKF, Freerez CLD, Permafresh EFR and CPD 3078-28A).
Conclusion	:	New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

25.10.2001 (29)

5.4 REPEATED DOSE TOXICITY

Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	gavage
Exposure period	:	90 days
Frequency of treatment	:	5 days/week
Post obs. period	:	no

Doses	:	1000; 3000; 6000 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL	:	1000 mg/kg/day
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity – Rodent: 90-day Study"
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result	:	10 male and 10 female rats were treated in each group. Three males of the 6000 mg/kg/day dosage level were found dead on study day three. The males of the 6000 and 3000 mg/kg/day dosage level groups exhibited a lower mean body weight gain. The mean body weights of the males of the 1000 mg/kg/day dosage level and of the treated female rats were comparable to controls throughout the study. Pharmacotoxic signs noted for male and female animals in the 3000 and 6000 mg/kg/day dosage level groups included primarily yellow discoloration of fur - anogenital region. In addition, male animals in the 6000 mg/kg/day dosage level group exhibited yellow discoloration of fur - abdominal region and soft stool. One male animal in the 6000 mg/kg/day dosage level group was noted for hypoactivity, decreased grasping reflex, extremities hypothermic to touch, and ataxia on study day 3. Other signs noted among rats of various dosage level groups, or controls, were considered incidental and unrelated to the test article. Macroscopically, one male from the 6000 mg/kg/day dosage level group was found at the post-mortem examination to have multiple yellowish linear macroscopic lesions in the right testis. No toxicologically significant organ weight changes occurred in this study. Microscopically, treatment related mild mineralization in the heart was seen in two males of the 6000 mg/kg/day dosage level group, in one of them a moderate bilateral mineralization of testes was also seen. Mineralization in the testes and heart were considered to be test article related lesions. No other macroscopic or microscopic findings were considered to be related to the test article.
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

28.12.01 (20)

Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	gavage
Exposure period	:	14 days (12 doses)
Frequency of treatment	:	daily (without weekend) with 3 consecutive administrations before the end of the study
Post obs. period	:	no
Doses	:	256; 640; 1600; 4000; 11680 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL	:	4000 mg/kg/day
Method	:	other: no further details given (pre-test for subchronic study)
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result	:	At 11680 mg/kg/day: There were no toxicologically significant macroscopic lesions or abnormalities with respect to organ weight. Microscopically, there were no special effects on tissues (with the exception of the nasal passages showing inflammatory reactions). Whereas 2 female control animals showed these inflammations on one side, all substance - treated

		animals had bilateral inflammations of the nasal passages. Lower doses: There were no microscopic changes of the nasal cavities or any other abnormal findings.
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

28.12.01 (20)

Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	gavage
Exposure period	:	90 days
Frequency of treatment	:	daily (without weekend)
Post obs. period	:	no
Doses	:	1000; 3000; 6000 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL	:	6000 mg/kg/day
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity – Rodent; 90-day Study"
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result	:	Mortality: 1 male animal died during the third week of treatment in the 3000 mg/kg/day group. Body weight gain: All dosed females showed an increased weight compared to the controls; the males of the 1000 and 6000 mg/kg/day group had the same or increased weight compared to the controls. The 6000 mg/kg/day group and controls showed no microscopically visible changes (the animals of the 1000 and 3000 mg/kg/day doses were not examined). Chronic interstitial pneumonia in the control and animals of the 6000 mg/kg/day group was seen in correlation with the positive finding of the Sendai-virus.
Test condition	:	Ten/sex/dose were treated with test material (3 doses) or water (control).
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

28.12.01 (19)

Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	gavage
Exposure period	:	14 days (12 doses)
Frequency of treatment	:	daily (without weekend) with 4 consecutive administrations before the end of the study
Post obs. period	:	no
Doses	:	256; 640; 1600; 4000; 11680 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL	:	11680 mg/kg/day
Method	:	other: no further details given
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 41.4% active ingredient, with 0.8 % formaldehyde present (remainder water).
Result	:	No deaths or substance-induced changes (clinical picture, body and organ

weights, micro- or macroscopic examinations) occurred.

Test condition : 5/sex/dose group were treated with each dose of test material or water (control)

Reliability : (2) valid with restrictions. Test material was a related chemical.

(19)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : Salmonella typhimurium TA102
Concentration : 1 - 5000 micrograms/plate (Plate incorporation test and Preincubation test); 2 - 10000 micrograms/plate (Preincubation test)
Cytotoxic conc. :
Metabolic activation : with and without
Result : negative
Method : OECD Guide-line 471 "Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay"
Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : The assay was performed in three independent experiments. Experiment I was performed as plate incorporation test and experiments II and III were performed as preincubation tests.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (14)

Type : Ames test
System of testing : Salmonella typhimurium strains TA98, TA100, TA1535, TA1537
Concentration : 33-10000 micrograms/plate (solvent DMSO); 333- 10000 micrograms/plate (solvent H_2O)
Cytotoxic conc. : 10000 mg/plate in most strains (produced slight to complete clearing of bacterial lawn depending on strain and test).
Metabolic activation : with and without
Result : equivocal
Method : other
Year : 1987
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). The analyzed purity was 41.4%. Since the test material is commercially available in water, it is likely that the majority of the impurity is water.
Remark : Because the tests with the two solvents were performed in different laboratories, it is difficult to discern whether the variable results were due to the tests being conducted in different laboratories or the use of different solvents.

It is also not known whether the test concentrations listed were corrected for test material purity.

Result : The test was valid, as positive controls were judged to be mutagenic. A questionable result was found in 2/4 tests (DMSO solvent) in strain TA100 incubated with S9-mix from hamster. In one test, the number of mutations at 10000 mg/plate was higher than control (182 +/- 4.6 vs. 123 +/- 3.1 in control) and in another the number of mutations at 6667 and 10000 mg/plate was higher than control (196 +/- 11.3 and 222 +/- 7.4, respectively vs. 150 +/- 10.0 in control). A questionable result also was found in 1/3 tests at 3333 and 10000 micrograms/plate (DMSO solvent) in strain TA100 incubated with S9-mix from rat (200 +/- 5.9 and 199 +/- 4.9 vs. 147 +/- 11.2 in control). A weakly positive result was found in 1/3 tests (DMSO solvent) in strain TA98 incubated with S9-mix from hamster. In this test, concentrations equal to or greater than 333 mg/plate appeared to increase the rate of mutations (ranged from 54 +/- 2.6 at 1000 mg/plate to 66 +/- 7.2 at 3333 mg/plate vs. 37 +/- 6.4 in control). All other tests with test material dissolved in DMSO solvent were negative.

A positive result was obtained with test material dissolved in water in strain TA100 incubated with S-9 from hamster or rat. The test in TA100 in the absence of S-9 had a questionable result (approximately a 30% increase in mutations at 3333 and 6667 mg/plate vs. control). In both the positive tests, dose-dependent increases in the number of mutations were observed, with an approximate 3-fold increase over control at the two highest concentrations in the presence of S-9 (6667 and 10000 mg/plate). A slight reduction of the bacterial lawn was noted at 10000 mg/plate in strain TA100. A weakly positive result was found in strain TA98 incubated with test material dissolved in water in the absence of S-9, or in the presence of hamster S-9 (approximately a 2-fold increase over control at the two highest concentrations that did not produce toxicity). The test with rat S-9 in this strain had a questionable result (a slight, dose-dependent increase).

Test condition : The test material was initially tested for toxicity to strain TA100 at the desired test concentrations. Nontoxic concentrations of test chemical (dissolved in DMSO or water), bacteria, and S-9 mix (10%)from liver of Aroclor1254-induced male rats or hamsters (or buffer) were incubated at 37 degrees C, without shaking, for 20 min. The top agar was added, and the contents of the tubes were mixed and poured onto the surface of petri dishes that contained Vogel-Bonner medium. At least 5 doses of test material were tested in triplicate. The histidine-revertant colonies were counted following 2 days of incubation. The maximum dose tested was 10 mg/plate. Concurrent solvent and positive controls (sodium azide for TA1535 and TA100, 9-aminoacridine for TA97 and TA1537, and 4-nitro-o-phenylenediamine for TA98) were run with each trial. The tests utilizing DMSO and water as the solvents were performed in different laboratories.

A chemical was judged to be mutagenic if a dose-related increase over the corresponding solvent control was seen, and was judged weakly mutagenic if a low-level dose response was seen. A trial was considered questionable if a dose-related increase was judged insufficiently high to justify a conclusion of weak mutagenicity, if only a single dose was elevated over control, or if a non dose-related increase was seen.

Conclusion	:	Test material was not mutagenic in strains TA1535 or TA1537. In the presence of S-9, approximately 50% of tests in strain TA100 were questionable in one laboratory (with test material in DMSO) and all tests were positive in the other laboratory (with test material in water). Weakly positive or questionable results were found in strain TA98 in the presence or absence of S-9 in the same laboratory that found positive results in strain TA100 (material was in water). One out of five tests in the other laboratory with strain TA98 in the presence of S-9 (and test material in DMSO) showed a weak response.
Reliability	:	(2) valid with restrictions. The test was only performed in 4 strains.

28.12.01 (26)(36)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	NMRI
Route of admin.	:	gavage
Exposure period	:	once
Doses	:	500, 1000, and 2000 (limit dose) as 75% solution in water
Result	:	negative
Method	:	OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year	:	1994
GLP	:	yes
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Contained 1% formaldehyde.
Test condition	:	Positive controls received 20 or 80 g/kg cyclophosphamide. Routine sampling of bone marrow was at 24 hrs for all doses and additionally at 48 hrs for the high dose.
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (13)

Type	:	Drosophila SLRL test
Species	:	Drosophila melanogaster
Sex	:	male
Strain	:	other: Canton-S
Route of admin.	:	oral feed
Exposure period	:	72 hours
Doses	:	60000 ppm
Result	:	positive
Method	:	other
Year	:	1984
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.
Method	:	Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark	:	It is unknown if the weight of the test material was corrected for purity. The criteria for significance are unconventional. The incidence of mutations in one control brood was high (3/1969 = 0.15%).
Result	:	None of the treated animals died. The frequency of sex-linked recessive

mutations in broods 1, 2, and 3 from males treated with test material was 4/2175, 6/2269, and 2/2117. One brood of controls had 3 mutations in 1969 chromosomes. Chromosomes from the 2 other control broods did not have any mutations. The total frequency of mutations in the treated group was 0.18% (vs. 0.06 in control). The substance was determined to be mutagenic in this test. The p value was not stated.

Test condition : Males were fed test material in water (or water vehicle) for 3 days. The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells over 7 days. A total of at least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value of < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%, and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.

Reliability : (4) unassignable. Test conduct does not appear to be robust.

28.12.01 (15)

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : other: injection
Exposure period : 24 hours
Doses : 60000 ppm
Result : positive
Method : other
Year : 1984
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.
Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : It is unknown if the weight of the test material was corrected for purity. The criteria for significance are unconventional. Fewer than 5000 control chromosomes were scored. One brood accounted for the majority of the mutations. Incidences in the 2 other treated broods were similar to controls. Standard deviations were not given.
Result : Test material caused 3% mortality. The frequency of sex-linked recessive mutations in broods 1, 2, and 3 from males treated with test material was 6/2160, 0/2043, and 2/1653. One brood of controls had 2 mutations in 1493 chromosomes. Chromosomes from the 2 other control broods did not have any mutations The total frequency of mutations in the treated group was 0.14% (vs. 0.05% in control). The substance was determined to be mutagenic in this test (although p values were not given).
Test conditions : Males were injected with test material (or water vehicle). The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells and over 7 days. A total of at least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value of < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%,

		and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.
Reliability	:	(4) unassignable. Test conduct does not appear to be robust

28.12.01 (15)

Type	:	other: Drosophila reciprocal translocation assay
Species	:	Drosophila melanogaster
Sex	:	male
Strain	:	other: Canton-S
Route of admin.	:	oral feed
Exposure period	:	72 hours
Doses	:	50000 ppm
Result	:	negative
Method	:	other: part of NTP genotoxicity program
Year	:	1984
GLP	:	yes
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%.
Method	:	Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark	:	The test was performed on the most sensitive brood of male germ cells identified in the injection SLRL test above. The result was considered positive if the reciprocal translocation rate was greater than a historical rage from 116,592 tests (0.0017%). At least 2 translocations out of 5000 tests were required to establish significance at the P <0.05 level.
Result	:	There were no reciprocal translocations in a total of 5611 chromosomes
Reliability	:	(2) valid with restrictions. Whether the results have been corrected for test material purity is unknown.

28.12.01 (15)

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

Type	:	other: examination of reproductive organs from 90-d repeated dose study
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	gavage
Exposure period	:	90 d
Frequency of treatment	:	5 times/week
Duration of test	:	90 days
Doses	:	up to 6000 mg/kg/day
Control group	:	yes, concurrent vehicle
Method	:	other: according to OECD guideline 408
Year	:	1983
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water).
Remark	:	additional information found in Section 5.4
Result	:	Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males treated with up to 3000 mg/kg/day

and females treated with up to 6000 mg/kg/day.

Reliability : (2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (20)

Type	:	other: examination of reproductive organs from 90-d repeated dose study
Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	gavage
Exposure period	:	90 d
Frequency of treatment	:	5 times/week
Duration of test	:	90 days
Doses	:	6000 mg/kg/day
Control group	:	yes, concurrent vehicle
Method	:	other: according to OECD guideline 408
Year	:	1984
GLP	:	no data
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water)
Remark	:	additional information found in Section 5.4
Result	:	Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males and females treated with up to 6000 mg/kg/day (referring to 100% substance).
Reliability	:	(2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (19)

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Wistar
Route of admin.	:	gavage
Exposure period	:	Day 7-16 of pregnancy
Frequency of treatment	:	daily
Duration of test	:	21 days
Doses	:	250; 500; 1000 mg/kg/day (64.1% test substance in water equivalent to 160, 320 and 640 mg/kg/day as 100% substance)
Control group	:	yes
NOAEL Maternalt	:	640 mg/kg bw
NOAEL Teratogen	:	640 mg/kg bw
Method	:	OECD Guide-line 414 "Teratogenicity"
Year	:	1998
GLP	:	yes
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 64% in water
Remark	:	23 mated females/group
Result	:	There were no deaths during the study. No clinical signs were observed in any of the animals. Body weights and food consumption were not affected by the administration of the test compound. No compound-related effects were observed at necropsy of the animals. Gravid uterus weights, crown-rump lengths, litter size, sex ratios, fetal and transplacental weights remained unaffected by the administration of the test compound. There

was no increase in the number of early or late conceptuses undergoing resorption. Morphological examination of the fetuses did not reveal any compound-related effect.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (18)

5.10 OTHER RELEVANT INFORMATION

Type : Toxicokinetics
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark : Patches of fabric soaked with ^{14}C-labelled test substance were applied to the dorsal skin of White New Zealand rabbits for 48 hours. 0.09 - 2.61% of the total ^{14}C labeling were retrieved in skin samples taking into consideration occlusion (1 – 1.4% after occlusive, ca. 0.1% after semi-occlusive), type of fabric and the specific perspiration of the skin. Perspiration almost doubled skin incorporation of radioactivity (ca. 2.6%) of the total dose in the cloth patches under occlusive conditions. Only < 0.02% was detectable in expired air as ^{14}C-CO_2. Only 0.001 to 0.006% of the activity was detected in muscle (back or thigh), fat, gonad, spleen, or brain. Higher levels were found in liver (0.117 - 0.205 % of dose), blood (0.058 - 0.095% at 4 hrs), and kidney (0.043- 0.070% of dose).
Reliability : (2) valid with restrictions. Test material was a related chemical.
28.12.01 (27) (28)

Type : Toxicokinetics
Test substance : Dimethyloldihydroxy-ethylene-urea
Remark : (^{14}C)-Dimethyloldihydroxy-ethylene-urea (^{14}C-DMDHEU) was stable to blood and skin (air) and was essentially unmetabolized (identity of HPLC radiograms of the composition of the test substance applied and the profile found after excretion). More than 95% of a 50 mg/kg intravenous dose to male F344 rats was excreted unchanged in the urine in 24 hr (85 % in 6 hr). Minor amounts were found in feces (2.2% in 24 hrs). Less than 0.2% was exhaled as $^{14}CO_2$ in 48 hrs. Tissues containing significant fractions of the dose after 0.5 hr were skin, muscle, blood, liver and kidney. By 72 hours, less than 0.5% of the dose remained in the tissues, mainly in muscle (0.3%).

After administration by gavage, the oral absorption of 14C-DMDHEU increased with increasing dose over the dose rage of 500-2000 mg/kg. An average of 17% of an approximately 500 mg/kg dose, 28% of an approximately 1000 mg/kg dose and 38% of an approximately 2000 mg/kg dose was absorbed. The distribution pattern was similar to that of i.v. injection. More than 90% of the radioactivity that was recovered in the urine was excreted within 24 hr. After 72 hours, residual quantities of radioactivity (< 10 micrograms DMDHEU equivalents/g tissue) were left in most tissues (higher amounts in intestine and cecum).

Dermal absorption of ^{14}C-DMDHEU from a non-occluded dose site over 144 h exposure period was approximately 5% of the applied dose (for doses of 13 and 3.5 mg/cm^2) and 1% of the applied dose (for a dose of 0.3 mg/cm^2). Partial occlusion of the dose site resulted in a more than 4-fold increase in dermal absorption, probably due to increased hydration of the skin. Distribution of ^{14}C in tissues following dermal exposure was

somewhat different than that observed following oral or intravenous dosing, with larger amounts of ^{14}C being found in adipose and smaller amounts in the muscles.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000, and SIDS initial assessment report for CAS No. 1854-26-8 9 (Reviewed at SIAM 10).

28.12.01 (22)

Type : Toxicokinetics
Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : A further study was conducted in the rhesus monkey, which is according to the investigator " the model more closely resembling human skin". Fabrics (96 cm^2) treated with ^{14}C-DMDHEU (prepared from ^{14}C-formaldehyde) were applied onto back skin of monkeys for 48 hours (either dry or with artificial perspiration). Even though the level of radioactivity used was low, essentially all of the ^{14}C-activity remained on the textile fabric (the level transferred to the skin was almost indistinguishable from background). An average of 0.12 microcuries of ^{14}C activity (equivalent to 0.029 %) could be detected in or on the skin lying underneath the fabric. No radioactivity (at or near background level) were detected in expired CO_2, urine, feces, blood, muscle, adipose, liver, lung, kidneys, spleen, brain and testes.
Conclusion : No appreciable penetration of test material from treated fabric was demonstrated
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(21)

5.11 EXPERIENCE WITH HUMAN EXPOSURE

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : One case of sensitization to dimethylol-dihydroxy-ethyleneurea was reported. Additional information is found in Section 5.3
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (16)

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : Thirty-seven substances which may be used in finishing textiles (including DMDHEU) were patch-tested in 66 patients who, anamnestically and/or clinically, were suspected of suffering from a textile finish contact eczema. In 27 patients, positive patch-test reactions to various textile finishes and additives were observed after 48-hr contact. Eight out of 24 patients tested for DMDHEU gave a positive response to DMDHEU (50 % in aqueous solution). Six out of these 8 patients also showed a positive response to formaldehyde (5 % in aqueous solution).

Additional information is found in Section 5.3
Reliability : (2) valid with restrictions. Test material was a related chemical.

28.12.01 (23)

Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Three different resins containing test material in 10% petrolatum [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] were patch tested on ten of 15 subjects with allergic textile dermatitis. Formaldehyde (2% in aqueous solution) was tested on all 15. The Calaroc PG and PK (not currently available) induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde. Additional information is found in Section 5.3
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Formaldehyde content of the different resins was not determined.

25.10.2001 (1)(12)(17)

Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde. Additional information is found in Section 5.3
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference (16) was not consulted.

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Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	One out of 6 subjects reacted to the test substance; none responded to formaldehyde.
Test condition	:	Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given. Additional information is found in Section 5.3
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

25.10.2001 (31)

Test substance	:	Dimethyloldihydroxy-ethylene-urea (DMDHEU; 4.5% in aqueous solution); Fixapret CPN
Remark	:	In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals.
Result	:	All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.
Test condition	:	Ten out of 12 subjects with positive patch-test reactions to older

formaldehyde resins were patch-tested with standard commercial allergens, formaldehyde (1% in aqueous solution), test substance (4.5% in aqueous solution), and 6 resins with low formaldehyde content (< 200 ppm).

Additional information is found in Section 5.3

Conclusion : New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins

Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (29)

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)

Remark : Case report of a 10-year-old boy with eczema on both shins wearing protective shin pads. He was patch tested with a standard series and a textile series. He showed positive reactions to DMDHEU (+/+, 4.5% in aqueous), formaldehyde (++/++), the formaldehyde releasing preservatives quaternium 15 ++/++ and imidazolidinyl urea (++/++), carba mix (+), dimethylol propylene urea (+/+), tetramethylol acetylenediurea (+/+), ethylene urea melaminie-formaldehyde resin (++/++, 5%), urea-formaldehyde resin 10% pet (++/++) and the epoxy hardener hexamethylenetetramine . He did not react to the sample of his shin pads.

Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (30)

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